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PharmaTech Solutions, Inc.

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

PHARMATECH SOLUTIONS, INC. **Plaintiff,** **vs.** **SHASTA TECHNOLOGIES, LLC,** **Defendant.**	**Case No.: 5:14-cv-03682 BLF** **DECLARATION OF KEITH BERMAN IN SUPPORT OF OPPOSITION TO MOTION TO DISMISS PURSUANT TO FRCP 12(b)(1) and 12(b)(6); AND** **Date:** April 16, 2015 **Time:** 9:00 a.m. **Place:** Courtroom 3, 5th FL

DECLARATION OF KEITH BERMAN

I, KEITH BERMAN, declare:

1. I am a resident of the County of Ventura, California. I have personal knowledge of all facts as stated in this Declaration. If called to testify, I can competently testify to the following.

2. Plaintiff PharmaTech Solutions, Inc. (hereafter "PharmaTech") is a Nevada Corporation.

3. Defendant Shasta Technologies, LLC (hereafter "Shasta"), is an Oregon limited liability company, with its principal place of business at 16923 SW Richen Park Circle, Sherwood, Oregon.

4. In 2010 and 2011, the dates of PharmaTech's two contracts with Shasta, Shasta was the owner of a product known as the GenStrip. The GenStrip is a diagnostic test strip to be used in conjunction with diagnostic test meters, i.e., devices that measure a person's blood sugar at any particular point in time. Shasta did not and has not owned any diagnostic test meters except perhaps for personal use. The GenStrip was physically manufactured for Shasta by a company called Conductive Technologies, Inc. (hereafter "CTI"), located in York, Pennsylvania.

5. On or about April 24, 2010, PharmaTech entered into an initial Exclusive Distributorship Agreement with Shasta, and Broadtree Inc. (hereafter "Broadtree"), an investor in Shasta, to distribute the GenStrip. The parties entered into a second Exclusive Distributorship Agreement on or about June 26, 2011.

6. As a result of a surprise inspection by the United States Food and Drug Administration (hereafter "FDA") of Shasta's alleged manufacturing facility for the GenStrip, which turned out to be nothing more than the home of one of its members, Calvin Knickerbocker, III, the son of Shasta's Managing Member Calvin Knickerbocker, Jr., PharmaTech was forced to establish a "nerve center" in York,

Pennsylvania to ensure that the GenStrip could continue to be manufactured, controlled and sold in accordance with the FDA's regulations. The establishment of this nerve center arises out of the following facts and circumstances.

7. During December 2013, I was informed by Calvin Knickerbocker III, the son of Shasta's Managing Member, Calvin Knickerbocker, Jr., that the United States Food and Drug Administration (hereafter "FDA") conducted a surprise inspection of Shasta's alleged manufacturing facility at 16923 SW Richen Park Circle, Sherwood, Oregon. Upon inspection, Shasta's alleged facility was determined to be only the residential home of Calvin A. Knickerbocker III. As such, the FDA determined that this residence was not a manufacturing facility, nor could any type of quality control and/or compliance with the FDA's regulation take place at this house. Indeed, the FDA issued a harsh Warning Letter to Shasta on April 8, 2014 setting forth the numerous violations discovered in its December inspection of Shasta's purported facility. To my knowledge, Shasta has never responded to this Warning Letter. (Exhibit A, attached to PharmaTech's Request for Judicial Notice, is a true and accurate copy of this Warning Letter that I printed from the FDA's Web Site.)

8. Thereafter, I learned from Mark DuVal, an attorney specializing in FDA compliance and regulation issues that was providing legal advice to both Shasta and PharmaTech with respect to the FDA problems arising from its surprise inspection of Shasta, that the FDA had no confidence that Shasta could continue act as the manufacturer and design specifier of the GenStrip. Accordingly, at Mr. DuVal's recommendation, PharmaTech agreed to become the manufacturer and design specifier of the GenStrip to keep the FDA from pulling the GenStrip from the market, as described more fully in the Declaration of Mark DuVal.

9. Thereafter, PharmaTech's Board of Directors, consisting of myself, located in Westlake, California, and Robert Jagunich, located in Northern California, and William Lyons, located in Naperville, Illinois, held a telephonic Board of Directors meeting on March 5, 2014 (prior to the filing of this action of on August 14, 2014) in an

attempt to prevent the FDA from issuing a directive removing the GenStrip from the market, and to keep the GenStrip product "alive." At this meeting, PharmaTech's Board of Directors resolved to: (i) execute a binding term sheet to purchase the GenStrip from Shasta; (ii) to hire a consultant, authorized by CTI to write and implement a suitable quality plan meeting all FDA standards and applicable regulations with respect to the GenStrip to be jointly administered by PharmaTech and CTI; (iii) to change the principal executive offices of PharmaTech to space located in CTI's office at 935 Borom Road, York Pennsylvania; and to register PharmaTech as a foreign corporation authorized to duly conduct business in Pennsylvania. (Exhibit A, attached hereto, is a true and accurate copy of this Board of Directors Resolution.)

10. PharmaTech has taken each of the above steps, including entering into a Quality Control Agreement with CTI on or about April 21, 2014. The FDA has also registered PharmaTech's 935 Borom Road York, Pennsylvania address as the official facility registration for PharmaTech, and PharmaTech has been certified by the Pennsylvania Secretary of State as a foreign corporation duly authorized to conduct business in Pennsylvania. (Exhibit B, attached hereto, is a true and accurate copy of this registration.)

11. Consistent with this agenda, on May 1, 2014, PharmaTech issued a press release to the general public that it had established its Quality Assurance and Quality Control Management and Polices in CTI's York, Pennsylvania offices, and that "[t]his office will centralize and manage the production and regulatory functions related to GenStrip manufacturing." (Exhibit C, attached hereto, is a true and accurate copy of this Press Release.)

12. As such, Shasta has confirmed in writing to the FDA that:

- Quality control of the GenStip exists and is maintained by CTI and PharmaTech;
- That MDR procedures had been developed, maintained, and implemented at CTI and PharmaTech;

- Procedures for management review exists and have been established by CTI and PharmaTech, and were in place on or around April 30, 2014;
- That Quality audits exist and are maintained by CTI and PharmaTech;
- That procedures for design control exist and are maintained by CTI and PharmaTech;
- That procedures for document control exist and are maintained by CTI and PharmaTech;
- That procedures for purchasing control exist and are maintained by CTI and PharmaTech; and
- A device master record exists and is maintained by CTI and PharmaTech.

(Exhibit D, attached hereto, is a true and accurate copy of a letter that I received which is authored by Shasta's Managing Member, Calvin Knickerbocker, Jr. to this effect.)

13. Accordingly, in performance of the above duties, I have been traveling to York, Pennsylvania on a regular basis, often every other week:

(i) to meet with CTI to insure compliance with PharmaTech's Quality Control Agreement with CTI, and all applicable FDA regulations;

(ii) to make, then and there, any decisions with respect to the same;

(iii) to make any future developmental plans for the GenStrip, including, but not limited to, quality control issues, audit procedure controls, Medical Device Reporting issues ("MDR" reviews), CTI management reviews, design control issues, document management and control issues, purchasing controls, and

(iv) to review the format, layout, abbreviation for expiration date and lot number for the distribution of the GenStrip, and to determine the useful shelf life of the GenStrip.

Consequently, PharmaTech's "nerve center" with respect to the GenStrip, is in York, Pennsylvania.

Consequently, PharmaTech's "nerve center" with respect to the GenStrip, PharmaTech's only business, is in York, Pennsylvania.

14. Conversely, PharmaTech has no Board of Director's meetings in Westlake, California, as its other two Board Members, Robert Jagunich, and William Lyons reside in Northern California and Illinois, respectively. As such, all Board Meetings are conducted by telephone.

15. There are no other officers at PharmaTech's Westlake address, except me, and I have an office there as I live in Westlake. Finally, while PharmaTech does have six or seven employees at the Westlake office, these employees merely operate PharmaTech's Call Center, i.e., the place where any customer complaints or other customer communications take place. These activities are goverened by another three Standard Operating Procedures in the CTI/PharmaTech QSR. Again, all oversight of the GenStrip, manufacturing, distribution, and compliance with FDA regulations, and bi-weekly meetings with CTI (increasingly more often), and other decisions respecting the GenStrip, occur in York, Pennsylvania.

16. In sum, as PharmaTech is not involved in the manufacturing or distribution of any other product, its "nerve center" with respect to the GenStrip, and hence its principal place of business, is in York, Pennsylvania, and cannot by regulatory representation and agreement, be at any other location.

I declare under the penalty of perjury that the forgoing is true and correct. Executed this 27th day of March 2015 at Westlake, California.

KEITH BERMAN

PHARMA TECH SOLUTIONS, INC.

A Nevada Corporation

EXECUTION OF BINDING TERM SHEET TO ACQUIRE GENSTRIP™ IP AND MARKS, HIRING OF CONSULTANT TO PREPARE USFDA MEDICAL DEVICE QUALITY AGREEMENT, CHANGE PRINCIPAL EXECUTIVE OFFICES TO YORK, PA UPON EXECUTION OF BINDING TERM SHEET, REGISTER WITH USFDA AS MEDICAL DEVICE MANUFACTURER OF GENSTRIP™

We the undersigned, representing all or a majority of Directors of Pharma Tech Solutions, Inc., a Nevada corporation, having met and discussed the business herein set forth, have:

RESOLVED, that the Board authorize the President to execute a binding term sheet with Shasta Technologies LLC for the purposes of acquiring its Genstrip™ product IP as well as its associated Marks.

RESOLVED, that the Board authorize the hiring of a consultant authorized by Conductive Technologies, Inc. to write and implement for the company a suitable Quality Plan meeting FDA standards for medical devices to be jointly administrated by the company and CTI as the integral part of the Genstrip™ IP and Mark acquisition.

RESOLVED, that the Board authorize the President to change the principal executive offices of the company to 925 Borom Road, York, PA 14701 as another integral part of the acquisition of the Genstrip™ product IP and its associated Marks .

FURTHER RESOLVED, that the Board authorize the President to incorporate the company as a foreign corporation in the State of Pennsylvania and to file any other documents necessary and appropriate.

FURTHER RESOLVED, that the company maintain its domicile in Nevada and to register as a foreign corporation in any other locale deemed desirable or necessary by the President resulting from these activities and/or necessary to maintain the company's enhanced standing with the USFDA.

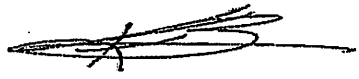
RESOLVED, that the Board authorize the President to execute the transfer of the FDA Registration of the Genstrip™ product into the current registration of the company with the USFDA, or any other registration method that is deemed necessary by the President as soon as is practicable.

FURTHER RESOLVED that the Board authorize the President immediately answer the FDA '483 letter received resulting from the USFDA inspection of March 2-4, 2014 wherein the company was inaccurately named by the USFDA, as of those dates, as the manufacturer of the Genstrip™ product.

RESOLVED THAT, the President or Secretary enforce those clauses in the Exclusive Distribution Agreement (2011) still in breach by Shasta Technologies LLC, in any manner deemed appropriate.

RESOLVED, that any actions taken by the Secretary to effect any of the resolutions captioned above or actions taken by the Secretary prior to or after this date be adopted hereby that are within the authority conferred thereby are hereby ratified, confirmed and approved as the acts and deeds of this corporation without further consideration by the Board.

DATED this 5th day of March 2014.



Keith Berman, Director

Robert Jagunich, Director

William Lyons, Director

DATED this 5th day of March 2014.

Keith Berman, Director

Robert Jagunich, Director

William Lyons, Director

DATED this 5th day of March 2014.

Keith Berman, Director

Robert Jagunich, Director

William Lyons, Director

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Registration Information

Get Help

Facility

Registration Number	3008282042
FEI Number	3008282042
Registration Status	Active
Registration Status Reason	TofO facility purchase
Initial Importer	N
Facility Name	PHARMATECH SOLUTIONS, INC
Facility Address	935 BOROM RD, YORK , PENNSYLVANIA , 17404 , UNITED STATES

Owner/Operator

Owner/Operator Number	10027212
Owner/Operator Contact Name	KEITH M BERMAN
Owner/Operator Business Name	PHARMA TECH SOLUTIONS, INC.
Owner/Operator Address	2660 TOWNSGATE ROAD SUITE 300 WESTLAKE VILLAGE , CALIFORNIA , 91361 , UNITED STATES
Owner/Operator Phone Number	805- 4462973
Owner/Operator Fax Number	805- 4461983
Owner/Operator E-mail	intermania@aol.com

Official Correspondent

Official Correspondent Contact Name	KEITH M BERMAN
Official Correspondent Business Name	GENSTRIP
Official Correspondent Address	2660 TOWNSGATE ROAD , SUITE 300 WESTLAKE VILLAGE , CALIFORNIA , 91361 , UNITED STATES
Official Correspondent Phone Number	805- 4462973
Official Correspondent Fax Number	805- 4461983
Official Correspondent E-mail	intermania@aol.com

Registration Status:

- EX. B -

News Room

SOURCE: Decision Diagnostics Corp.

May 01, 2014 09:20 ET

GenStrip Opportunity Expands Under Full Control of DECN's PharmaTech Division

LOS ANGELES, CA--(Marketwired - May 1, 2014) - Decision Diagnostics Corp. (OTCQB: DECN), and its subsidiary Pharma Tech Solutions, the FDA registered manufacturer and owner/operator for the popular GenStrip™ 50, a medical device specifically designed to work with the Johnson & Johnson's LifeScan Ultra family of glucose testing meters, today added clarification to its discussion about its recently acquired GenStrip product. The company stated that there is no question that GenStrip was born of the highest manufacturing practices and adheres closely and consistently meets or exceeds its own documented specifications cleared by the FDA in November 2012.

GenStrip has always been safe, effective, reliable and in full compliance with stringent regulatory procedural standards. The recent FDA letter was singularly directed to Shasta Technologies LLC. No other company was included, either, directly or indirectly. PharmaTech was in full agreement with the FDA in its criticism of the deficiencies of the Shasta quality procedures and monitoring system. That shared opinion significantly contributed to the acquisition of GenStrip and the immediate quality and regulatory oversight that is now provided by PharmaTech.

Mark DuVal, President of DuVal & Associates, P.A., an attorney with 30 years' of FDA legal experience and current regulatory counsel to PharmaTech states, "The FDA abstractly talks about a deficient quality system by a previous company named Shasta. The quality system deficiencies stated do not relate to PharmaTech or the actual safety or effectiveness of the GenStrip product, which is safe and effective and always has been."

The GenStrip product, currently available through retailers across the nation, was manufactured by an FDA registered and ISO certified contract manufacturing facility that is respected throughout the industry. This manufacturer, Conductive Technologies, Inc. ("CTI"), adheres to consistent and rigid quality procedures. All of the products CTI produces routinely exceed the standards established by FDA. In order to reinforce its concerns about quality systems, PharmaTech has established its QA/QC Management and Policies office within CTI's facilities. This office will centralize and manage the production and regulatory functions related to GenStrip manufacturing. We will also be better able to improve the responsiveness of manufacturing to customer needs particularly functions related to our new Private Label brand strategy.

Keith Berman, President of PharmaTech, said, "PharmaTech has decided to subtly change the packaging of our existing Genstrip product with our newly rebranded GenStrip 50. GenStrip 50 can be immediately viewed at www.pharmatechdirect.com/genstrip.html. Our last several weeks have been active and positive as we are hitting our stride. We have acquired GenStrip, assumed manufacturing and quality control, and are ready to aggressively move it forward. The market remains huge, we are perfectly positioned, and the opportunity still available for our taking."

Mr. Berman concluded, "The company's Board plans to announce a date for a shareholder conference call soon after we file our Annual Report on Form 10-K with the SEC. This conference call will focus on the progression of our GenStrip manufacturing and quality plan, our new Discretion product, our pending uplist to OTCQX, and a discussion of our GenStrip opportunities."

Forward-Looking Statements:
This release contains forward-looking statements about our business or financial condition that reflect our assumptions and beliefs based on information currently available. We can give no assurance that the expectations indicated by such forward-looking statements will be realized.

There may be other risks and circumstances that we are unable to predict. When used in this release, words such as "believes," "expects," "forecasts," "intends," "projects," "plans," "anticipates," "estimates" and similar expressions are intended to identify forward-looking statements, although there may be certain statements not accompanied by such expressions.

For further information about GenStrip 50, please visit the company's Web Sites: www.decisiondiagnostics.com or www.pharmatechdirect.com.

GenStrip™ test strips are not manufactured, distributed, endorsed, or approved by nor associated with LifeScan®, Inc., a Johnson & Johnson®

-EX. C -

Company, manufacturers and distributors of the OneTouch® Ultra® Family of Meters and OneTouch® Ultra® test strips.

CONTACT INFORMATION

Contact:
Decision Diagnostics Corp.
Keith Berman
(805) 446-2973
info@decisiondiagnostics.com

News Room

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From this industry	Medical and Healthcare
	Pharmaceuticals and Biotech
From this sub-industry	Healthcare
	Drugs
	Equipment and Supplies
	Biotech

SHASTA TECHNOLOGIES, LLC
SHERWOOD, OREGON

December 30, 2013

Sherri N. Rohlf
Stanley B. Eugene
Investigators
US Food and Drug Administration
22215 26th Ave SE Suite 210
Bothell, WA 98021

Subject: Response to FDA 483: Dates of establishment inspection 12/02/2013 – 12/09/2013

Dear Investigators Rohlf and Eugene,

I am the President of Shasta Technologies, LLC and as such have the authority to respond to the Form FDA483 Inspectional Observations from your establishment inspection that started on 12/02/2013 and ended on 12/09/2013. We at Shasta Technologies, LLC are committed to full cooperation with the agency and for compliance with all FDA rules and regulations.

Before specifically commenting on the FDA 483 observations, which are attached to this letter, I would like to further explain the current functioning status of Shasta Technologies, LLC (Shasta) and our GenStrip® Glucose Test Strip (GenStrip) product.

Shasta was founded with the concept of developing and obtaining FDA 510(k) clearance of the GenStrip Glucose Test Strip. As with virtually all start-up companies who are not associated with other larger companies, Shasta had a very basic design development process that relied on the verification and validation testing done as part of the 510(k) submission. As a result, the design development of the GenStrip was an iterative process which directly involved the FDA through the correction of the 510(k) submission deficiencies. At the time of FDA clearance, the GenStrip specifications and design development were ended.

Shasta has only three employees including me. This management team has had experience obtaining FDA clearance of two other glucose test strip devices in the past and one of the management team was Director of Diabetes Research for LifeScan, Inc., manufacturer of the LifeScan Ultra test Strip which served as the 510(k) predicate for the GenStrip. He was responsible for their development and is one of the foremost experts in this technological arena.

The firm is not involved with any other FDA regulated product. Shasta was never established with the intention of expanding into a manufacturer of medical devices. The company exists to hold ownership of the GenStrip 510(k), the GenStrip intellectual property, and to enter into contractual relationships with other companies who have the special knowledge, expertise, and

EX. D -

equipment to manufacture and distribute our FDA cleared GenStrips in full compliance with all relevant FDA regulations. We understand that the agency is used to conventional company organizations and this virtual organization is not typical, but is increasingly the way in which medical device technology is being funded, developed, manufactured and commercialized with specialized parties performing their respective roles. Having stated that, we understand and respect the agency's concerns about creating and exercising proper management of respective authority within the quality system.

Although Shasta is currently registered as a specification developer with FDA, as stated above, the further development of the GenStrip ended with the 510(k) clearance of the product. The GenStrip specifications are unchanged since FDA clearance.

During this establishment inspection, there was a comment on the change in the GenStrip product labeling allowing the use of the GenStrip test strips with LifeScan meters manufactured through July 2013 (moved from 2010) and the lack of another cleared 510(k). This labeling change was carefully evaluated by our legal counsel who, after examining FDA's guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device," dated January 10, 1997 (hereinafter the "Modifications Guidance"), opined that a new 510(k) was unnecessary. The appropriate letter to file was prepared and is in the GenStrip design history file at our contract manufacturer Conductive Technologies, Inc. (CTI).

The inspectional observations are stated below with our responses.

Respectfully yours,

Calvin A. Knickerbocker, II
President
Shasta Technologies, LLC

cc: Mark DuVal, DuVal and Associates, P.A.

Attachments:

Appendix A: Shasta Technologies LLC Quality Manual
Appendix B: GenStrip Master Quality Plan

OBSERVATION 1

Quality system procedures and instructions have not been established.

Specifically,

Your firm maintains no documented quality system procedures.

SHASTA RESPONSE

Actually a robust quality system does exist and has been maintained at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. Shasta Technologies LLC has prepared a new Quality Manual Doc No. QS-1001, effective date December 31, 2013, describing the quality system appropriate for a specification developer who utilizes contract manufacturers to conduct the majority of all operations. Additionally, Shasta Technologies, LLC has formalized the relationships with the contract manufacturers as defined in the GenStrip Master Quality Plan.

This Shasta Technologies LLC Quality Manual is attached in Appendix A and the GenStrip Master Quality Plan is attached in Appendix B.

OBSERVATION 2

Written MDR procedures have not been developed, maintained, and implemented.

Specifically,

Your firm has not defined, documented, and implemented medical device reporting (MDR) procedures.

SHASTA RESPONSE

MDR procedures have been developed, maintained and implemented at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. A description of Shasta Technologies LLC complaint and MDR handling are contained in Quality System Doc No QS-1001 Section 14.0 Corrective and Preventive Action. Section 14.1 Corrective Action describes the procedure for customer complaints and MDR regarding the identity, quality, durability, reliability, safety, effectiveness, or performance of a product. Customer complaints are currently handled by Pharma Tech Solutions in accordance with the GenStrip Master Quality Plan in Appendix B.

OBSERVATION 3

The quality policy and was not established by management with executive responsibility.

Specifically,

You firm has not defined, documented, and implemented a quality policy.

SHASTA RESPONSE

A quality system policy does exist and has been established with executive responsibility at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. The Quality Manual Doc No. QS-1001 Section (i) Introduction and Scope and 1.0 Management Responsibility defines the Shasta Technologies LLC Management responsibility, quality policy, organizations, and responsibility and authority.

OBSERVATION 4

Procedures for management review have not been established.

Specifically,

Your firm has not established procedures for management reveiw.

SHASTA RESPONSE

Procedures for management review do exist and have been established at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. The Quality Manual Doc No. QS-1001 section 1.4 Management Review outlines the structure of Shasta Technologies LLC management review. Because of the limited nature of Shasta Technologies' operation as a specification developer, the company plans to participate in the contract manufacturer's routine review using the contractor's own quality procedures of GenStrip manufacturing and distribution. The initial management review is to be completed within 60 days of the date of this response but no later than by February 28, 2014

OBSERVATION 5

Procedures for quality audits have not been established.

Specifically,

Your firm has not defined, documented, and implemented a quality audit procedure.

SHASTA RESPONSE

Procedures for quality audits do exist and have been maintained at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. The Quality Manual Doc No. QS-1001 section 17.0 Internal Quality Audits describes the procedure to be used by Shasta Technologies LLC in conducting quality audits. These audits will be accomplished in association with our contract manufacturers.

OBSERVATION 6

Quality audits have not been performed.

Specifically,

Your firm has not conducted a quality audit.

SHASTA RESPONSE

A quality audit of Pharma Tech Solutions and Conductive Technologies, Inc. was performed in August 2013. Although this internal audit was not performed in accordance with this new Quality Manual, Shasta Technologies LLC believes it was thorough and rigorous and met the requirements of the QSR regulations. The GenStrip Glucose Test Strip product has only been marketed for two months and more product needs to be manufactured, sold and the quality system exercised before another audit. Future routine quality audits will be conducted by August 2014.

OBSERVATION 7

Procedures for design control have not been established.

Specifically,

Your firm does not maintain design control procedures covering the GenStrip glucose test strips.

SHASTA RESPONSE

Procedures for design control do exist and have been maintained at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. As discussed during the FDA inspection, Shasta has taken the position that the initial cleared GenStrip Glucose Test Strip with the validations and testing required by FDA as part of that clearance constitute the initial revision of the GenStrip. Shasta Technologies started with the

idea of the GenStrip, not with a quality system. The quality system became necessary once the GenStrip was cleared for use.

As part of the Quality Manual Doc No. QS-1001 Section 4.0 Design Control was prepared to comply with the QSR requirements. However, Shasta Technologies relies heavily on the design control procedures of our contract manufacturers to comply with the QSR requirements.

OBSERVATION 8

Document control procedures have not been established and maintained.

Specifically,

Your firm has no document control procedures.

SHASTA RESPONSE

Procedures for document control do exist and have been maintained at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. Quality Manual Doc No. QS-1001 section 5.0 Document and Data Control describes the document control procedures. A majority of the GenStrip Glucose Test Strip manufacturing, quality, and distribution documentation is maintained by our contract manufacturers. However, Shasta Technologies specific document handling capabilities are being prepared and will be completed within 60 days or by February 28, 2014.

OBSERVATION 9

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically,

Your firm has not defined, documented, and implemented purchasing control procedures. Your firm contracts out manufacturing, marketing, and complaint handling for GenStrip gJucose test strips.

SHASTA RESPONSE

Procedures for purchasing control do exist and have been maintained at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. Quality Manual Doc No. QS-1001 section 6.0 Purchasing Control describes the Shasta Technologies LLC procedure for purchasing materials and services.

Because Shasta Technologies is a specification developer our contract manufacturers are our most important service. This procedure allows a supplier to be approved in many different ways. Certification to an FDA accredited quality standard such as ISO 13485 2003 is sufficient evidence to approve a supplier. Our main contract manufacture, Conductive Technologies, is ISO 13485 certified.

OBSERVATION 10

The evaluation of potential suppliers and contractors was not documented.

Specifically,

Your firm does not maintain documented evaluation of suppliers and contractors you use to conduct manufacturing, marketing, and complaint handling for GenStrip glucose test strips. For example, your firm does not maintain documented evaluation of activities your contract manufacturer conducts, including process validation, nonconforming product, acceptance activities, labeling, and packaging in the manufacture of GenStrip glucose test strips.

SHASTA RESPONSE

Shasta Technologies is in the process of addressing the continued qualification of our contract manufacturers. This will be accomplished by participation in routine management review meeting and yearly internal audits. Both internal audits and management reviews will be conducted in cooperation with our contract manufacturers. Our first management review will be completed on or before February 28, 2014

OBSERVATION 11

Procedures for corrective and preventive action have not been established.

Specifically,

Your firm has not defined, documented, and implemented a corrective and preventive action procedure.

SHASTA RESPONSE

Quality Manual Doc No. QS-1001 section 14.0 Corrective and Preventive Action describes the Shasta Technologies CAPA activities. Because all of the manufacturing and distribution is performed by our contact manufacturers, Shasta Technologies relies on our contractor's CAPA procedures for the actual investigation. Shasta Technologies will be notified by our contract manufacturers of any CAPAs to closing. To date there have been no GenStrip Glucose Test Strip CAPAs.

OBSERVATION 12

A device master record has not been maintained.

Specifically,

Your firm does not maintain a device master record for GenStrip glucose test strips.

SHASTA RESPONSE

A device master record does exist and have been maintained at Conductive Technologies, Inc. and Pharma Tech Solutions. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. Quality Manual Doc No. QS-1001 Section 16.0 Control of Quality Records addresses the need for a DMR at the contract manufacturer (section 16.1). Conductive Technologies which is Part 11 compliant maintains all GenStrip Glucose Test Strip records in electronic form. These records are available to Shasta Technologies at any time.

OBSERVATION 13

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically,

Your firm has not defined, documented, and implemented complaint handling procedures.

SHASTA RESPONSE

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit do exist and have been maintained at Conductive Technologies, Inc. and Pharma Tech. We understand the FDA's position, however, that Shasta, even as a specification developer, must have certain matters as to its role covered within a quality system. As noted in Observation 2 a description of Shasta Technologies LLC complaint are contained in Quality System Doc No QS-1001 Section 14.0 Corrective and Preventive Action. Section 14.1 Corrective Action describes the procedure for customer complaints regarding the identity, quality, durability, reliability, safety, effectiveness, or performance of a product. Customer complaints are currently being implemented and documented by Pharma Tech Solutions in accordance with the GenStrip Master Quality Plan in Appendix B.